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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,518

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Jacques Marie Rene Jan Huyghe

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EXAMINER

YANG, ANDREW

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,518	Applicant(s) HUYGHE ET AL.	
	Examiner ANDREW YANG	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11,21-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11,21-27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicant's amendment filed on August 13, 2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 and 21, 24-27, and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickman (U.S. Patent No. 7066960) in view of Stubstad et al. (U.S. Patent No. 3867728).

Dickman discloses an intervertebral disc prosthesis 100. Disc prosthesis 100 is substantially the same as disc 50 (Column 12, Lines 15-20) as stated in the disclosure. Disc prosthesis has a flexible section 52 and a less flexible portions 103, 104. The less flexible portions 103, 104 are endplates that are provided on the bottom and top side of the flexible portion 52 as well as an inner side. The prosthesis is also fiber reinforced with a sheath 51. The fiber material has a low elasticity modulus (Column 8, Lines 1-6) and is considered capable of absorbing hydrogel monomers. The prosthesis 100 for replaces of an intervertebral disc of a human. The core has swelling characteristics comparable to a natural intervertebral disc (Column 5, Lines 64-66). Since the hydrogel can remain in liquid or semi-liquid state, it will have swelling characteristics comparable to those of a natural intervertebral disc. The fibers are woven/knit to have a criss-cross

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pattern (Column 8, Lines 1-5) and then can be considered to be wound around a hydrogel.

Dickman fails to disclose the less flexible portion also covered in fibers. Stubstad et al. teaches in intervertebral prostheses with a flexible portion 15 and a less flexible portion 11, 12. The flexible portion and less flexible portions 11, 12 which are endplates, are covered in whole by fibers. The fibers on the less flexible portions are provided to enhance tissue ingrowth (Column 4, Lines 18-21). It would have been obvious to one skilled in the art at the time the invention was made to provide the less flexible portions of Dickman with fibers in view of Stubstad in order to enhance tissue ingrowth.

With regard to claims 8-10, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the flexible portion of Dickman as modified by Stubstad having thickness of 5-15mm or 8-10 mm and also having at least 5% fibers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Dickman and Stubstad fail to disclose the fibers to be made of polyurethane. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Dickman as modified by Stubstad et al. with polyurethane fibers, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

With regard to claims 24-27, 29, and 30 it should be noted that applicant is claiming an article of manufacture and not the process of forming/making the device, accordingly, the manner in which the device is formed, i.e. winding or knitting, slicing, is given little weight as long as the final product is shown. The burden is upon the applicant to come forward with evidence establishing an unobvious difference between prior art and the current application. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Claims 1 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickman (U.S. Patent No. 7066960) in view of Stubstad et al. (U.S. Patent No. 3867728) in view of Bao et al. (U.S. Patent No. 5047055) and further in view of Stoy (U.S. Patent No. 6264695).

Dickman and Stubstad et al. disclose the claimed invention except for reducing the volume of the implant prior to insertion by soaking the implant in a salt bath. Bao et al. teaches a hydrogel implant for an intervertebral disc that is implanted in a human (Column 7, Lines 30-40). Prior to implanting the volume of the prosthesis is reduced by dehydration so as to reduce the size of the implant for insertion (Column 7, Lines 55-60). It would have been obvious to one skilled in the art at the time the invention was made to reduce the size of the device of Dickman as modified by Stubstad by dehydration prior to inserting further in view of Bao et al. in order to reduce the size of the implant for insertion.

Bao et al. fails to disclose dehydrating by immersing the implant in a hypertonic salt bath. Stoy teaches using a salt bath to reduce the volume of the prosthesis in order to not completely dehydrate the implant and avoiding making the implant brittle for

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insertion (Column 13, Lines 10-15). It would have been obvious to one skilled in the art at the time the invention was made to reduce the volume of the device of Dickman as modified by Stubstad and Bao et al. by using a salt bath further in view of Stoy in order to prevent the implant from becoming brittle for insertion.

Response to Arguments

In response to Applicant's argument that Dickman fails to disclose the fibers wound around the composite prosthesis, this argument is moot since the Examiner uses Stubstad et al. as a teaching for fibers wound around the entire prosthesis. Thus Dickman in view of Stubstad discloses the claimed feature.

In response to Applicant's argument that the fibers of Dickman are not capable of absorbing hydrogel monomers, the Examiner respectfully disagrees. The fibers absorb some of the hydrogel mixture from the center (Column 7, Lines 40-44) and thus are shown to be able to absorb a hydrogel and therefore capable of absorbing hydrogel monomers.

In response to Applicant's argument that the flexible portion does not have swelling characteristics comparable to those of a natural intervertebral disc, the Examiner respectfully disagrees. It has been shown in the art that hydrogels used in the art for spinal procedures have the property of having swelling properties similar to those of the natural intervertebral disc as seen in U.S. Patent No. 5,047,055, which is cited by Dickman. Furthermore, as claimed, the swelling characteristics only need to be comparable to those of a natural disc, meaning having the ability to be compared to a

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natural disc, in which case any material used for the flexible portion can be compared to a natural disc.

In response to Applicant's argument that Dickman and Stubstad fail to disclose a the claimed prosthesis having fibers wound around the whole flexible portion and the less flexible portion, the Examiner respectfully disagrees. Stubstad teaches a spinal prosthesis where every externally exposed surface has fibers and thus has fibers wound around the entirety. Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). In the instant case, the structural limitation of fibers wound around the flexible portion and at least one less flexible portion has been met.

With regard to claims 24-27, 29, and 30 the Examiner maintains that they are product-by-process claims. Furthermore it is noted that Stubstad anticipates or renders obvious at least claims 24-26 as fiber 29 is wound around the hole of flexible portion and is also wound on at least one less flexible portion.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
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